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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/266,803      | 03/12/1999  | GREGORY M. GLENN     | PM-256865           | 6258             |

7590 03/17/2004  
Morgan, Lewis & Bockius LLP  
1111 Pennsylvania Avenue, N.W.  
Washington, DC 20004

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| EXAMINER |
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EWOLDT, GERALD R

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| ART UNIT | PAPER NUMBER |
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1644

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |  |                                     |  |
|------------------------------|--|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/266,803   | <b>Applicant(s)</b><br>GLENN ET AL. |  |
|                              | <b>Examiner</b><br>G. R. Ewoldt, Ph.D. | <b>Art Unit</b><br>1644             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2003 and 27 January 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 112-133 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 112-133 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

#### DETAILED ACTION

1. Applicant's amendment and remarks, filed 12/02/03, and IDS, filed 1/27/04, are acknowledged.

2. New Claims 112-133 are pending and under examination.

3. In view of Applicant's amendment and remarks all previous rejections have been withdrawn. In particular, Applicant has withdrawn all of the previous claim language that required new matter rejections and all of the limitations that required enablement rejections.

4. The following are new grounds for rejection necessitated by Applicant's amendment or actions.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 117, 123, 125, and 127 and are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) a "live virus" (Claim 117),

B) the "formulation comprises an ADP-ribosylating exotoxin B subunit" (Claim 123),

C) the "an ADP-ribosylating exotoxin, exotoxin subunit, or toxoid chemically conjugated to a carbohydrate, polypeptide, glycolipid, or glycoprotein" (Claim 125),

D) "the formulation is applied to intact skin covering more than one draining lymph node field" (Claim 127).

Regarding A), support has been found for "live attenuated virus" but not the broader "live virus".

Regarding B), support has been found only for the B subunit of cholera toxin.

Regarding C), no support has been found as set forth above.

Regarding D), support has been found for "a defined set of lymph nodes (e.g., cervical, axillary, inguinal, epitrocheal, popliteal, and those of the abdomen and thorax)", but not the broader "more than one draining lymph node field".

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 120 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claim 120 is indefinite as it comprises an improper Markush group. Note that in the instant context chemokines, cytokines, etc. are subgenres of the adjuvant genus. Tumor necrosis factor alpha is a species of the cytokine subgenus. Accordingly, the claim should properly recite the subgenres, e.g., cytokine etc., and an additional dependent claim should recite, the species tumor necrosis factor alpha, e.g., "wherein the cytokine is tumor necrosis factor".

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 112-133 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 32 of copending Application No. 10/633,626. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a method comprising inducing an immune response comprising applying a formulation comprising an antigen and an adjuvant to hydrated skin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 112-133 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 32 and 33 of copending Application No. 10/701,069. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a method comprising inducing an immune response comprising applying a formulation comprising an antigen and an adjuvant to hydrated skin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 112-133 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 17 of copending Application No. 10/435,676. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a method comprising inducing an immune response comprising applying a formulation comprising an antigen and an adjuvant to skin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. No claim is allowed.

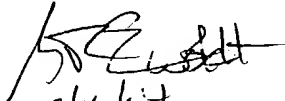
14. Applicant's amendment or action (filing of new applications) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

16. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

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3/16/07  
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